

Applicants: Arlindo L. Castelhano, et al.
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Remarks

Claims 76-110, 114-124, 128-131 and 133-135 were pending in the subject application. By this amendment applicants have canceled claims 103-109. Accordingly, claims 76-102, 110, 114-124, 128-131 and 133-135 are currently pending.

Double Patenting - Claims 99 and 133-135

On pages 3-6 of the July 28, 2004 Office Action, the Examiner rejected claims 99 and 133-135 under the judicially created doctrine of obviousness-type double patenting. In particular, the Examiner alleged that 1) claim 99 is unpatentable over claims 1 and 4-6 of U.S. Patent No. 6,686,366 ("the '366 patent"); 2) claims 133-135 are unpatentable over claims 41-46 of the '366 patent; and 7) claim 133 is unpatentable over claim 36 of U.S. Patent No. 6,680,322.

1) Claim 99

Applicants maintain that the compound claimed in claim 99 is a later filed improvement over the compounds claimed in the '366 patent. Applicants point out that the '366 patent discloses 1) A3 receptor antagonist compounds which were first disclosed in PCT International Application No. PCT/US99/12135, filed June 1, 1999, and 2) A3 receptor antagonist compounds which were disclosed for the first time in the application, filed December 2, 1999, which became the '366 patent. However, the '366 patent claims only the genus of compounds disclosed in PCT International Application No. PCT/US99/12135, filed June 1, 1999, and does not claim any specific compounds which were disclosed for the first time in the application filed December 2, 1999 which became the '366 patent.

The compounds first disclosed December 2, 1999 are improved compounds in that they selectively bind to the adenosine A3 receptor with an affinity that is at least 10 times greater than

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their affinity for adenosine A1, A2a or A2b receptors (see Specification page 186, Table 15). Thus, the specific compound of pending claim 99 is an improvement over the compounds encompassed by claims 1 and 4-6 in the '366 patent.

It is unexpected that from the June 1, 1999 disclosure of a genus of compounds and certain specific compounds one could select a specific compound like the one in pending claim 99. As such, Applicants contend they are entitled to claim this specific compound which is an improvement over the prior art. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this double patenting rejection in its entirety.

2) Claims 133-135

The Examiner cited In re Durden, 763 F.2d 1405 (Fed.Cir. 1985) in support of the rejection of claims 133-135. In re Durden held that under a specific set of facts, the use of a novel and unobvious starting material or final product does not render an obvious, predictable process patentable. Later cases such as In re Ochiai, 71 F.3d 1565 (Fed.Cir. 1995), however, limit In re Durden to its facts. In other words, *per se* rules are inapplicable when determining obviousness. According to the more recent case law, all claim limitations must be considered during interpretation of a claimed invention.

Applicants contend that the process of claims 133-135 is not obvious. The claimed R5 groups of the starting material in step a) in combination with the claimed R1 groups of the intermediate reactant in step d) are not claimed by any of the patents that the Examiner cited. In fact, claims 133-135 refer to claim 76, which the Examiner acknowledges is patentable. Clearly, the subject application does not use identical reactants as those

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claimed in the cited patents.

As such, the chemical process cannot be an expected reaction based upon the prior art. Indeed, it would not have been obvious to those of ordinary skill in the art to choose the particular starting material and intermediate reactants because they were unknown but for the December 2, 1999 disclosure on which this application is based. In re Ochiai at 1569-70.

Moreover, the possibility that one of the reactants of the methods disclosed in U.S. Patent Nos. 6,686,366 and 6,680,322 could be modified to one of the reactants of the subject application does not make the method obvious "unless the prior art suggested the desirability of such a modification." In re Gordon, 733 F.2d 900, 902 (Fed.Cir. 1984). The Examiner has not asserted the existence of such a suggestion.

In view of the preceding discussion, applicants respectfully request that the Examiner reconsider and withdraw this double patenting rejection in its entirety.

Section 112 Paragraph 1 - Claims 103-109

On pages 6-10 of the July 28, 2004 Office Action, the Examiner rejected claims 103-109 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

In response, to advance prosecution, without conceding the correctness of the Examiner's argument or relinquishing their right to pursue patent protection for any canceled subject matter, applicants have canceled claims 103-109. For the record, however, applicants maintain that their invention includes the use of prodrugs to generate the claimed compounds *in vivo*. Consequently, the rejection is now moot.

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Section 112 Paragraph 2 - Claims 117 and 118

On page 10 of the July 28, 2004 Office Action, the Examiner rejected claims 117 and 118 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements.

In response, applicants point out that claims 117 and 118 recite a method of treating "a disease associated with an A3 adenosine receptor" which is "associated with mast cell degranulation." It is known in the art that the A3 adenosine receptor has been implicated in mast cell degranulation. Mast cell degranulation is not a singular disorder, *per se*, but rather represents an immunological responsive state which triggers various diseases (see Specification pages 13-16). The compounds claimed in claims 117 and 118 are known to treat mast cell degranulation.

Thus, applicants contend that the additional limitation requiring that the diseases associated with mast cell degranulation be recited in the claim unnecessarily limits the claims. Consequently, applicants contend that the claims as written clearly describe the subject matter being claimed. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Conclusion

Applicants respectfully submit that the accompanying amendments and remarks serve to place all of the pending claims in condition for allowance.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number

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provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

Gary J. Gershik

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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